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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,972	KRAMER ET AL.	
	Examiner	Art Unit	
	George R Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44 and 46-54* is/are pending in the application.

4a) Of the above claim(s) *9-12* is/are withdrawn from consideration.

5)☒ Claim(s) *40-44* is/are allowed.

6)☒ Claim(s) *1-39, 46-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 9-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/16/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not described in the original specification is having the one or more sensed parameters "based on said one or more selected cardiac conduction times" when they are selected from the group of cycle length, activity level, and minute ventilation. The original specification described the use of sensors to determine the sensed parameters (page 4, lines 10 and 27, page 8, lines 17-21, page 9, line 13, page 12, line 19, page 14, line 12, etc).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6, and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 4 and 6, "sensed parameters" lack antecedent basis and the claims are incomplete for omitting a step for sensing parameters.

In claim 54, "the template" lacks antecedent basis and it is unclear what element or step "the template" is referring to, how it is generated, and if it is generated based on any other step or element in the claim. The examiner is unclear what step or element is being claimed in step (d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 13-21, 23, 24, 26-39, 46, and 49-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Bornzin (5891176). Bornzin teaches the use of mapping the AV interval to the different activity ranges and with the use of heart rate (the claimed cycle length) to determine an AV interval for programming into the pacemaker. In addition, Bornzin states in column 8 that the samples are taken every hour every day and the first 12 hours of the first day and the second 12 hours of the second day will therefore meet the claimed limitations of "different times in

successive 24 hour periods" (it is noted that the claims are open ended "comprising" claims). Also, the A-V interval will be both dynamic and fixed since it is fixed until the next mapping and it is dynamic since it can change after each mapping. Finally, Bornzin states in columns 8 and 9, that the routine may be activated in response to certain conditions, such as the activity level.

Claims 1-8, 13-20, 27-39, and 50-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Turcott et al (6792310). Turcott states in columns 6 and 9 that multiple different parameters such as A-V, V-V (the claimed cycle length) or heart rate (also the claimed cycle length) can be adjusted over their ranges to determine and program the optimum A-V, V-V, and heart rate. In addition, the programmed A-V, V-V, and heart rate will be both dynamic and fixed since the optimization can run indefinitely or run for a programmed number of times and then fix the parameter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 23, 25, 26, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Turcott et al (or Bornzin for claims 22, 25, 47, and 48).

Turcott (or Bornzin) discloses the claimed invention except for enabling a manual trigger mode for trending conduction times for a specific exercise (claims 22, 25, 47, and 48) and collecting conduction time data based on a sensed parameter (claims 23, 26, and 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pacer optimization routine as taught by Turcott (or Bornzin), with enabling a manual trigger mode for trending conduction times for a specific exercise and collecting conduction time data based on a sensed parameter since it was known in the art that pacer optimization routines use enabling of a manual trigger mode for trending conduction times for a specific exercise, such as a stress test, to provide a programmer/physician a means to start the routine during a stress test to make sure the pacer is operating properly, that the correct pacing parameter is programmed, and that the routine is operated over the complete range of activity and/or heart rates and since it was known that pacer optimization routines use collection of conduction time data based on a sensed parameter to provide an automatic method to start the system when a sensed parameter meets a predetermined condition.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bornzin (or Turcott).

Bornzin (or Turcott) discloses the claimed invention except for the template generated with a look up table. It would have been obvious to one having ordinary skill in the art at the

time the invention was made to modify the method of providing optimized pacing as taught by Bornzin (or Turcott), with the template being generated with a look up table since it was known in the art that pacing methods and systems use look up tables to generate elements, such as templates, to provide a quick and preprogrammed way to determine a generation of an element, such as a template, that does not involve using processor power or time to perform calculations to compute the element.

Allowable Subject Matter

Claims 40-44 are allowed.

Response to Arguments

Applicant's arguments filed 12/27/04 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the elimination of the use of physiological sensors to detect changes in cardiac performance) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not say that a physiological sensor can NOT be used to determine a range of activity levels. In addition, the specification does NOT say physiological sensors should not be used. The specification says exactly the opposite in that sensors can be used, as seen in the specification on page 4, lines 10 and 27, page 8, lines 17-21, page 9, line 13, page 12, line 19, page 14, line 12, etc. In addition, it is unclear how the activity level and minute ventilation (claims 4, 6, 17, etc.) are determined if physiological sensors are not used. The argument that Bornzin does not trend data over a range of activity levels is not

persuasive since Bornzin teaches the use of mapping the AV interval to the different activity ranges and with the use of heart rate (the claimed cycle length) to determine an AV interval for programming into the pacemaker.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762
2/14/5

GRE
February 14, 2005